

R E M A R K S

Claims 1 to 9 and 12 as set forth in Appendix II of this paper are now pending in this case. Claims 10 and 11 have been canceled, and Claim 4 has been amended, as indicated in the Listing of Claims set forth in Appendix I of this paper.

Applicants have amended Claim 4 to depend upon Claim 3 instead of Claim 1. Claims 3 refers to "a reducing agent" and therefore provides antecedent basis for -the reducing agent- mentioned in Claims 4. No new matter has been added.

The Examiner has rejected Claims 4, 10 and 11 under 35 U.S.C. §112, ¶2. Withdrawal of the respective rejection is respectfully solicited in light of the foregoing amendment of Claim 4 and the cancellation of Claims 10 and 11. In light of the latter it is also respectfully requested that the rejection of Claims 10 and 11 under Section 101 be withdrawn. Favorable action is solicited.

The Examiner has rejected Claims 1 to 9 and 12 under 35 U.S.C. §102(b) as being anticipated by the teaching of *Denzinger et al.* (US 4,402,937).

Denzinger et al. disclose a process for the preparation of PVP-iodine wherein iodine is added to an aqueous PVP solution. *Denzinger et al.* further provide that the PVP employed in the process has a K value of from 8 to 50, and that the aqueous PVP solution contains from 10 to 60% by weight of PVP, wherein the higher concentrations pertain to PVP having a low K value. The latter information merely acknowledges the fact that the viscosity of an aqueous PVP solution

- increases, at a given concentration, with increasing K values, and
- increases, at a given K value, with an increase in the concentration.

Since the formation of PVP-iodine is, per se, slow it is necessary that the viscosity of the reaction mixture is low to ensure as good an intermixture as possible. Consequently, a person of ordinary skill in the art will employ a highly concentrated PVP solution only where

the PVP has a low K value, and will employ PVP solutions of low concentration when the K value of the PVP is high. The principle is applied by *Denzinger et al.* in examples A and B¹⁾. In example A, the PVP has a K value of 12.5, and the concentration is adapted to 50%, whereas in example B, where the PVP has a K value of 17, the concentration is adapted to 40%. Apart from the foregoing, *Denzinger et al.* fail to provide any information pertaining to the concentration of the aqueous PVP solution which is employed in the process. Anticipation requires that the identical invention is shown in the reference in as complete detail as is contained in the claim²⁾. The showing of the reference may be expressly or inherently, but each and every element as set forth in the claim it has to be found in the reference³⁾. *Denzinger et al.* clearly fails to expressly show the particular requirement that the PVP concentration be adapted to meet the relation

$$C > 100 \times [0.1 + 8 : (K + 5)]$$

which characterizes applicants' invention. Moreover, *Denzinger et al.* also fail to inherently describe the requisite limitation.

None of the representative examples described by *Denzinger et al.* meets applicants' requirement which is evident when the K values and the concentration of the PVP solutions employed by *Denzinger et al.* are reviewed:

- In Example 1, *Denzinger et al.* employ a PVP solution in accordance with example I of DAS 2,818,767⁴⁾ which has a concentration of 30% and wherein the PVP has a K value of 31.5⁵⁾.
- In Examples 2 and 5a to 5c, *Denzinger et al.* employ a PVP solution in accordance with example II of DAS 2,818,767⁶⁾ which has a concentration of 40% and wherein the PVP has a K value of 16.6⁷⁾.

1) col. 4, indicated lines 17 to 49, of *US 4,402,937*

2) *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (CAFC 1989)

3) *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (CAFC 1987)

4) col. 5, indicated lines 53 to 55, of *US 4,402,937*; DAS 2,818,767 corresponds to *US 4,200,710* (note the priority data indicated in [30] on the face of the patent) a copy of which is herewith enclosed for the Examiner's convenience

5) compare col. 4, indicated lines 17 to 36, particularly line 34, of *US 4,200,710*

6) col. 6, indicated lines 12 and 13, and lines 54 and 55, of *US 4,402,937*

7) compare col. 4, indicated lines 38 to 58, particularly lines 55 and 56, of *US 4,200,710*

- In Example 3, *Denzinger et al.* employ the PVP solution obtained in method A which has a concentration of 50% and wherein the PVP has a K value of 12.5.
- In Example 4, *Denzinger et al.* employ the PVP solution obtained in method B which has a concentration of 40% and wherein the PVP has a K value of 17.

The respective data are compiled in the following table together with the minimum concentration which is required in accordance with applicants' invention

Example No.	PVP Solution		C ^(a) [wt-%]
	K Value	concentration [wt-%]	
1	31.5	30	31.9
2	16.6	40	47.0
3	12.5	50	55.7
4	17	40	46.4
5a	16.6	40	47
5b	16.6	40	47
5c	16.6	40	47

C^(a) is the concentration which equals $100 \times [0.1 + 8 : (K + 5)]$ and which has to be exceeded in accordance with applicants' invention. It is immediately apparent from the data provided in the table that the PVP solutions employed by *Denzinger et al.* in all cases have a concentration which is from about 6% (Example 1) to about 15% (Example 2) below the concentration C^(a) which has to be exceeded in accordance with applicants' invention.

In light of the foregoing, the disclosure of *Denzinger et al.* fails to show, explicitly or inherently, applicants' invention in as complete detail as is contained in applicants' claims. The disclosure is therefore insufficient to anticipate applicants' invention within the meaning of Section 102. Favorable reconsideration of the Examiner's position and withdrawal of the respective rejection is respectfully solicited.

For completeness sake, the following is respectfully submitted to show that applicants' invention is not rendered obvious within the meaning of Section 103(a) by the disclosure of *Denzinger et al.*

In PVP-iodine preparation and storage a number of specific problems are encountered. On the one hand, storage may result in iodine

loss⁸). On the other hand, when the process is adapted to reduce the iodine loss, excessively long reaction times become necessary and/or agglomeration occurs when the reaction mixture is heated⁹). *Denzinger et al.*'s teaching aims at improving the storage stability of aqueous PVP-iodine solutions¹⁰). The problems which are due to prolonged reaction times and agglomeration are not mentioned. Accordingly, a person of ordinary skill in the art finds nothing in the disclosure which suggests or implies means that are suitable to reduce the reaction times and to avoid PVP-iodine agglomeration.

Applicants have now found that the reaction times are significantly reduced and the agglomeration of PVP-iodine is avoided when the PVP concentration in the reaction mixture exceeds a particular value which depends, in the manner set forth in applicants' formula, upon the K value of the PVP. The respective effect is illustrated in the experiments reported on page 11 et seq. of the application. In accordance with the comparative example¹¹) the reaction time is 21 hours agglomeration occurs, whereas, in accordance with applicants' invention, the the reaction times are from 4 to 11 hours and no agglomeration is observed.

The disclosure of *Denzinger et al.* is therefore insufficient to render applicants' invention *prima facie* obvious within the meaning of 35 U.S.C. §103(a).

In light of the foregoing and the attached, the application should be in condition for allowance. Early action is solicited.

REQUEST FOR EXTENSION OF TIME:

It is respectfully requested that a one month extension of time be granted in this case. A check for the \$110.00 fee is attached.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees, to Deposit

8) for example *Denzinger et al.*, and page 1, indicated lines 24 to 28, of the application

9) for example, page 1, indicated line 37, to page 2, indicated line 7, and comparative example page 11, indicated lines 31 to 40, of the application.

10) for example col. 2, indicated lines 60 to 62, of US 4,402,937

11) page 11, indicated lines 31 to 40, and the data compiled in Table 1, page 14, of the application

Account No. 11.0345. Please credit any excess fees to such deposit account.

Respectfully submitted,
KEIL & WEINKAUF



Herbert B. Keil
Reg. No. 18,967

1350 Connecticut Ave, N.W.
Washington, D.C. 20036
(202) 659-0100

Encl.: THE LISTING OF CLAIMS (Appendix I)
THE AMENDED CLAIMS (Appendix II)
copy of US 4,200,710 (Denzinger et al.)

HBK/BAS

APPENDIX I:

THE LISTING OF CLAIMS (version with markings):

1. (original) A process for preparing polyvinylpyrrolidone-iodine in aqueous solution, where an aqueous polyvinylpyrrolidone solution and at least 4.0% by weight of elemental iodine, based on the polyvinylpyrrolidone calculated as solid, are mixed, wherein at the time of mixing the concentration c of the aqueous polyvinylpyrrolidone, based on the total amount of polyvinylpyrrolidone and water, and the K value of polyvinylpyrrolidone obeys the following relation:

$$c > 100 \times [0.1 + 8 : (K + 5)]$$

where c is stated in % by weight, and the Fikentscher K value is in the range from 10 to 100.

2. (original) A process as claimed in claim 1, wherein the mixture is heated at a temperature in the range from 50 to 110°C for a period of from 30 minutes to 15 hours.
3. (previously presented) A process as claimed in claim 1, wherein the mixing is carried out in the presence of a reducing agent.
4. (currently amended) A process as claimed claim [+] 3, wherein the reducing agent is selected from formic acid, oxalic acid, the esters and salts of formic and oxalic acids, and the amides of carbonic acid, of formic acid and of oxalic acid.
5. (previously presented) A process as claimed in claim 1, wherein the polyvinylpyrrolidone solution and, where appropriate, at least part of the reducing agent are mixed, the mixture is heated where appropriate, and then iodine is added.
6. (previously presented) A process as claimed in claim 1, wherein a polyvinylpyrrolidone solution of a polyvinylpyrrolidone with a K value of > 27 and a polyvinylpyrrolidone content of > 35% by weight is employed.
7. (previously presented) A process as claimed in claim 1, wherein the polyvinylpyrrolidone-iodine present in the solution has an available iodine content of at least 4% by weight.
8. (previously presented) A polyvinylpyrrolidone-iodine solution obtainable by a process as claimed in claim 1.

9. (original) A solid polyvinylpyrrolidone-iodine obtainable by removing the water and other volatile constituents from an aqueous polyvinylpyrrolidone-iodine solution as defined in claim 8.
10. (canceled)
11. (canceled)
12. (previously presented) An antiseptic composition comprising an aqueous polyvinylpyrrolidone-iodine solution as defined in claim 8 or solid polyvinylpyrrolidone-iodine obtainable by removing the water and other volatile constituents from an aqueous polyvinylpyrrolidone-iodine solution.